2020 CAP Accreditation Checklist Updates: Changes That Matter

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DECEMBER 16, 2020

Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

Objectives

- Describe key changes and the rationale for the changes in the CAP Accreditation Program requirements.
- Use CAP resources to identify changes.
- Implement any necessary changes to ensure compliance with new accreditation requirements.

Summary of Changes in 2020

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	196	0	16	0	1
BAP	180	0	5	0	1
CBG	73	0	4	0	0
CHM	160	1	2	0	0
COM	82	2	18	0	0
CYG	69	0	3	0	0
CYP	80	0	2	0	1
DRA	20	0	1	0	0
FDT	115	0	2	0	2
FLO	49	0	2	0	0
GEN	245	3	27	0	1
HEM	180	0	10	0	3
HSC	147	0	1	0	1
IMM	65	1	0	0	0
LSV	281	8	8	0	3
MIC	257	4	8	1	2
MOL	170	0	10	0	0
POC	62	1	0	0	0
RLM	116	1	2	0	1
TRM	261	6	16	0	33
URN	27	0	3	0	0
TOTAL	**2835**	**27**	**140**	**1**	**49**

Topics for 2020 Checklist Update

- **Laboratory General Checklist (GEN)**
  - **Quality Management (QM)**
  - **Laboratory Computer Services**
  - **Infection Prevention and Reporting**

Topics for 2020 Checklist Update, Cont'd

- **All Common Checklist (COM)**
  - **Proficiency Testing**
  - **Comparability of Instruments and Methods-Nonwaived Testing**
  - **Reagents**
  - **Instruments and Equipment**
  - **Test Method Validation and Verification**
- **Discipline-specific checklist changes (ANP, CHM, IMM, MIC, POC, TRM)**
- **CAP resources to identify changes**

Topics for 2020 Checklist Update, cont'd

- **The following materials are available in the toolkit:**
  - **Summary of the discipline-specific checklist changes**
  - **Instructions for downloading checklists (including "Changes Only" version)**

http://appsuite.cap.org/appsuite/learning/LAP/FoC_Webinars/2020ToolkitChecklistUpdate.pdf

Laboratory General

Quality Management

GEN.20316 QM Indicators of Quality

- Requires the monitoring of key indicators of quality in all phases of testing with comparison of performance against laboratory-defined targets.
  - Added **new examples** of key quality indicators.

Troponin Turnaround Time	**Specific clinical stat turnaround time metrics (eg, order to result availability, specimen collection to result availability)**
Laboratory Test Utilization	**Percent of tests (or a test) that appear to be redundant, excessive or noncontributory to good patient care.**

  - Updated references to include newer CAP Q-PROBE studies for identifying benchmarks.

Your laboratory is expected to:

- Compare quality indicator performance against laboratory-defined targets
- Monitor key indicators integral to patient care delivery

Quality Management, cont'd

GEN.20318 Corrective and Preventive Action

- Added **new** QM requirement for **corrective** and **preventive** action.

You must have QM processes for:

- **Recording corrective/preventive** action
  - Errors and incidents (ie, nonconforming events)
  - Quality indicators not meeting defined targets
- Evaluating the effectiveness of actions taken

Quality Management, cont'd

GEN.20326 Assessment of the QM Program Implementation

- Previously GEN.16902 QM Program Implementation
- Clarified the scope of QM program effectiveness assessment performed at least annually to include:
  - Performance of quality indicators
  - Effectiveness of actions when targets are not met
  - Follow-up of issues (nonconforming events) requiring action
  - Actions taken for reported safety/quality concerns
- Added guidance for selection/retention/retirement of quality indicators
- Provided examples of how to record results of QM assessment

GEN.20326 Scenario

While inspecting a laboratory, the inspector asks for records of the QM program effectiveness review and is shown a dashboard report signed by the quality manager and the laboratory director showing the laboratory's performance on its quality indicators.

Is this laboratory in compliance?

Quality Management

GEN.20377 Record/Specimen Retention

- Added a **recommendation** for retaining specimens for patients admitted for **suspected drug overdose:**
  - Ideal specimens include a urine specimen and gray top tube (or other serum specimen) collected as soon as possible upon hospital admission
  - Specimens should be retained:
    - At least 30 days after presentation to hospital **or**
    - At least 48 hours after hospital discharge or death

You should discuss this recommendation with the emergency department and physicians to identify practices appropriate for your setting.

*Relevant article: Prahlow JA, Brooks eg, Jones P Jr. Drug overdose deaths and toxicology tests: let's talk. *CAP Today*. 2018 Dec.

Quality Management, cont'd

GEN.20430 Verification of Records Prior to Destruction

- **NEW Phase II requirement for laboratories to ensure that records (patient reports, worksheets, quality control records) converted onto another medium for storage and retention are verified before original records are destroyed:**
  - **Content adopted from (previous) TRM.32350 (Records QC)**
  - **Applicable to all areas of the laboratory**

You can ensure compliance by:

- **Implementing a process to verify "copies of records" for:**
  - **Accuracy**
  - **Legibility**
  - **Completeness**

Laboratory Computer Services

- **GEN.43022 LIS Testing**
  - **Modified the NOTE for testing new or modified computer programs to include assessment of the live (production) system after implementation.**

- **GEN.43875 Autoverification Validation**
  - **Eliminated annual retesting of the autoverification process.**
  - **You must validate your autoverification rules:**
    - **Initially and**
    - **Whenever there are changes that may affect the autoverification algorithm**

Laboratory Computer Services, cont'd

GEN.48500 Interface Result Integrity

- **Eliminated biennial verification of interface result integrity.**
- **You must verify electronic transmission of patient results to the patient report:**
  - **Initially and**
  - **Whenever there are changes that may affect the accuracy of transmission**

GEN.41316 – COVID-19 Test Result Reporting

- **GEN.41316 Infectious Disease Reporting**
  - **Modified to require reporting of all results of testing intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19 to state or local health authorities, including:**
    - **Positive and negative results**
    - **Molecular, antigen, and antibody test methods**
    - **Laboratories with all types of CLIA certificates**
  - **Changes are effective immediately for all laboratories subject to US regulations**
    - **Based on new CLIA regulations**
    - **Non-compliance may result in sanctions and civil money penalties from CMS**

**** Read the eAlert for more detailed information***

Infection Prevention and Control (formerly Bloodborne Pathogens)

- **GEN.74050 Specimen Handling/Processing**
  - **NEW requirement (adapted from MIC.63220) for laboratories to safely handle specimens suspected to contain highly infectious pathogens.**
  - **You should review national, federal, state (or provincial) and local guidelines for handling of samples suspected to have high risk pathogens such as:**
    - **Avian influenza**
    - **MERS coronavirus**
    - **SARS coronavirus**
    - **COVID-19 coronavirus**

TB Exposure Plan

GEN.74900 Tuberculosis (TB) Exposure Plan

- Modified the requirement for the **TB Exposure Control Plan** to align with **recent guidelines** from the Centers for Disease Control (CDC) to include:
  - TB exposure screening for personnel exposed to TB at **defined intervals** for all personnel identified to be **at risk** for occupational exposure
  - Use of **engineering** and **practice controls** for hazardous activities that may **potentially** aerosolize *M. tuberculosis*

What you need to do to be compliant:

- Review **latest CDC recommendation**
  https://www.cdc.gov/nchhstp/newsroom/2019/recommendations-for-tb-screening.html
- **Perform risk assessment** for TB exposure for all laboratory personnel
- Perform **baseline** screening of all personnel
- **Identify** personnel previously exposed with potentially infectious TB
- **Determine** appropriate **TB testing intervals** for your site

TB Exposure Plan, cont'd

GEN.74900 Tuberculosis (TB) Exposure Plan

- **Serial (eg, annual) screening is not indicated for personnel without latent TB infection if:**
  - **There is no known exposure and**
  - **In settings where there is no evidence of ongoing TB transmission**
- **Serial screening is indicated for:**
  - **Personnel at increased occupational risk for TB exposure or**
  - **In settings where transmission has occurred in the past**
- **The CDC recommends annual TB education for all personnel (including TB exposure risks).**
- **Screening must comply with state/local regulations.**

All Common Checklist Changes

Proficiency Testing

COM.01100 Ungraded PT Challenges

- **Modified and expanded requirement for assessing ungraded PT challenges.**
- **Examples of ungraded PT challenges requiring assessment include:**
  - **PT challenges that were intended to be graded, but were not, for reasons such as:**
    - **Submission of results after the cut-off date**
    - **Lack of submission of results**
    - **Result form completed incorrectly (eg, wrong method code, result entered in the wrong place)**
    - **Lack of consensus**
- **Educational PT challenges (NEW)**

Scenario: COM.01100

You are inspecting a laboratory's PT reports and noticed that for the educational challenge the supervisor simply dated and initialed the report. When you reviewed the Participant Summary report, you realized that the laboratory's results varied from the intended results.

Should the laboratory be cited for COM.01100, Ungraded PT Challenges?

COM.01100, cont’d

How should my laboratory record review of ungraded PT challenges?

Activity Menu

COM.01200 Activity Menu

- Requires laboratories to ensure that their CAP Activity Menus **accurately** reflect testing performed.
- Modified the **NOTE** to:
  - Provide **pathway** for updating activity menu on cap.org using Organization Profile in e-LAB Solutions Suite
  - Clarify when to include **research testing** as an activity

Must include on activity menu when patient-specific results are reported.
May include testing if performed solely for research if the laboratory wishes it to be inspected.

Comparability of Instruments and Methods-Nonwaived Testing

COM.04250 Comparability of Instruments and Methods – Nonwaived Testing

- **Modified NOTE to clarify the applicability of the requirement and materials used for comparability studies.**

You must compare nonwaived methods/instruments twice a year for tests performed on:

- **The same or different instrument makes/models**
- **Different methods, even if there are different reference intervals or levels of sensitivity**
- **Primary and back-up methods used for patient testing**
- **Examples of suitable materials for comparability studies include:**
  - **Patient/client specimens (pooled or unpooled) – preferred**
  - **Quality control materials for tests performed on same instrument platform and reagent lot**
  - **Alternative protocols based on quality control or reference materials validated (when applicable) to have the same response as fresh human samples**

Scenario: COM.04250

My laboratory performs COVID-19 molecular testing using four different platforms and in multiple laboratory sections.

- **Are comparisons required every six months for each platform?**
- **Do we need to compare antigen and PCR COVID-19 tests also?**

Scenario: COM.04250, cont'd

- **Our back-up instrument is used rarely (if ever). Do we still need to do comparisons twice a year?**
- **We perform electrolytes on a nonwaived POCT analyzer and in the main laboratory. Do we need to compare them?**
- **I have two identical instruments that perform the same test. Can we use our QC to compare the instruments twice a year?**

Reagents

COM.30400 Reagent Expiration

- Combined requirements on reagent expiration from the Anatomic Pathology, Biorepository, Histocompatibility, and Transfusion Medicine Checklists for standardization.
- Added language to the **NOTE** from deleted checklists items to address:

Rare red cell panels/rare antisera/selected cells beyond the expiration dates in transfusion service laboratories
Suitable control materials or technical assessment of case material containing suitable material for evaluation of stains in histology and cytology

- You must continue to follow manufacturer's defined expiration dates, unless a specific exception defined in the checklist applies.

Instruments and Equipment

COM.30690 Calibration/Recalibration - Ocular Micrometer

- **NEW** requirement to **calibrate** the ocular micrometer for different types of testing such as:
  - Parasitology ID of bloodborne parasites
  - Sperm morphology classification (as required by classification method)
  - Microscopic measurements of surgical pathology specimens (eg, measuring thickness of invasive melanoma)
- **Combined** requirements from the Hematology (HEM.34660, HEM.34665), Microbiology (MIC.51210, MIC.51220), Reproductive Laboratory Medicine (RLM.06450), and Limited Services (LSV.43864, LSV.45315, LSV.45320) Checklists.

What you need to do to be compliant:

- Perform **initial calibration** of ocular micrometers against a calibrated stage micrometer slide/object of **known** dimension
- **Recalibrate** with changes to the optics of the microscope (eg, objective or ocular lens)
- Retain records of calibration/recalibration (as applicable)

Test Method Validation and Verification

COM.40300 Verification of Test Performance Specifications

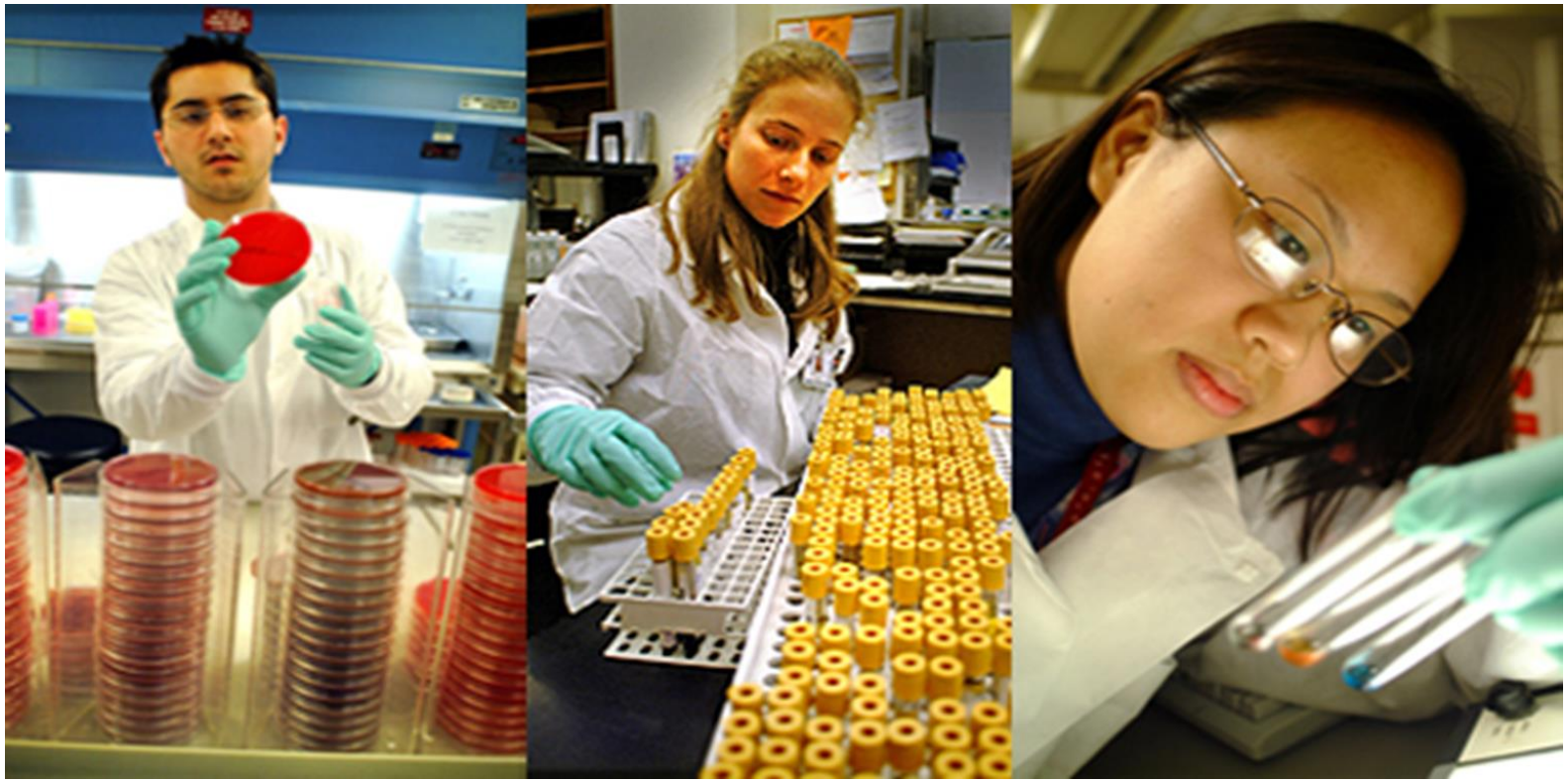
- **Added new content to the NOTE to address the laboratory's role in test method verification when FDA-cleared or approved methods are verified by non-laboratory personnel:**

  "If an FDA-cleared or approved method was verified by someone other than the laboratory's personnel (eg, manufacturer's representative), the laboratory must ensure that the verification correlates with its in-house test performance by showing confirmation of performance specifications by laboratory personnel testing known specimens."

Test Method Validation and Verification, cont'd

- **Does this mean that verification studies on new instruments can no longer be contracted by a third-party vendor?**
- **What can I show to an inspector to demonstrate compliance?**

Discipline-Specific Checklist Changes



Discipline-Specific Checklist Changes

HIV Primary Diagnostic Testing: Supplemental and Confirmatory Testing

- **NEW requirements to follow public health guidelines* for supplemental and confirmatory HIV testing.**
- **Added to the Microbiology (MIC.65620), Chemistry (CHM.33790), Immunology (IMM.41450), and Point-of-Care (POC.08640) Checklists.**
- **Applies to HIV primary diagnostic testing only.**
- **If additional testing after primary screening test is recommended by public health authorities, you must:**
  - ***Perform** additional reflex testing if specimen is suitable and testing performed is performed on site*
  - ***Send** additional testing to a referral laboratory if specimen is suitable **or***
  - *Provide **guidance** to providers on submission of additional specimens*

***Review the updated CDC/APHL algorithm at https://www.aphl.org/aboutAPHL/publications/Documents/ID-2019Jan-HIV-Lab-Test-Suggested-Reporting-Language.pdf.**

Discipline-Specific Checklist Changes, cont'd

Rapid Detection of *Mycobacterium Tuberculosis* Complex

- **NEW phase I requirements: MIC.32150 and MIC.32170.**
- **Only applies to testing done for patients suspected of having pulmonary tuberculosis.**
- **Testing to be performed on at least one respiratory specimen (preferably first diagnostic specimen).**

MIC.31250 – Laboratories subject to US regulations	MIC.32170 – Laboratories not subject to US regulations
• Requires availability of a nucleic acid amplification test for rapid detection of *M. tuberculosis*	• Requires availability of a nucleic acid amplification test or use of the country/region testing algorithm for rapid detection of *M. tuberculosis*

- **Testing can be done on site or by a referral laboratory.**
- **Based on Centers for Disease Control and Prevention (CDC) and World Heath Organization (WHO) recommendations.**

Discipline-Specific Checklist Changes, cont'd

MIC.21835 Direct Identification and Susceptibility from Blood Culture Broth

- Revised to limit applicability of the requirement to direct testing from **blood culture broth** (previously addressed all direct testing methods).
- **Clarified** that the laboratory director can determine the **extent** of **confirmatory testing** based on the manufacturer's recommendations and through review of verification/validation data.

MIC.22635 Blood Culture Contamination

- **NEW** item on monitoring **blood culture contamination** rates and establishing an acceptable threshold.
- **Tracking** contamination rates and providing feedback to collectors can reduce your rate.
- Factors that may affect contamination rate may include:
  - Effect of line draws
  - Type of skin disinfectants used
  - Training of personnel used to collect specimens

Discipline-Specific Checklist Changes, cont'd

ANP.12075 Residual Frozen Tissue

- **Modified the NOTE to expand the list of exceptions* for making paraffin blocks and stained slides following a frozen section examination to include:**

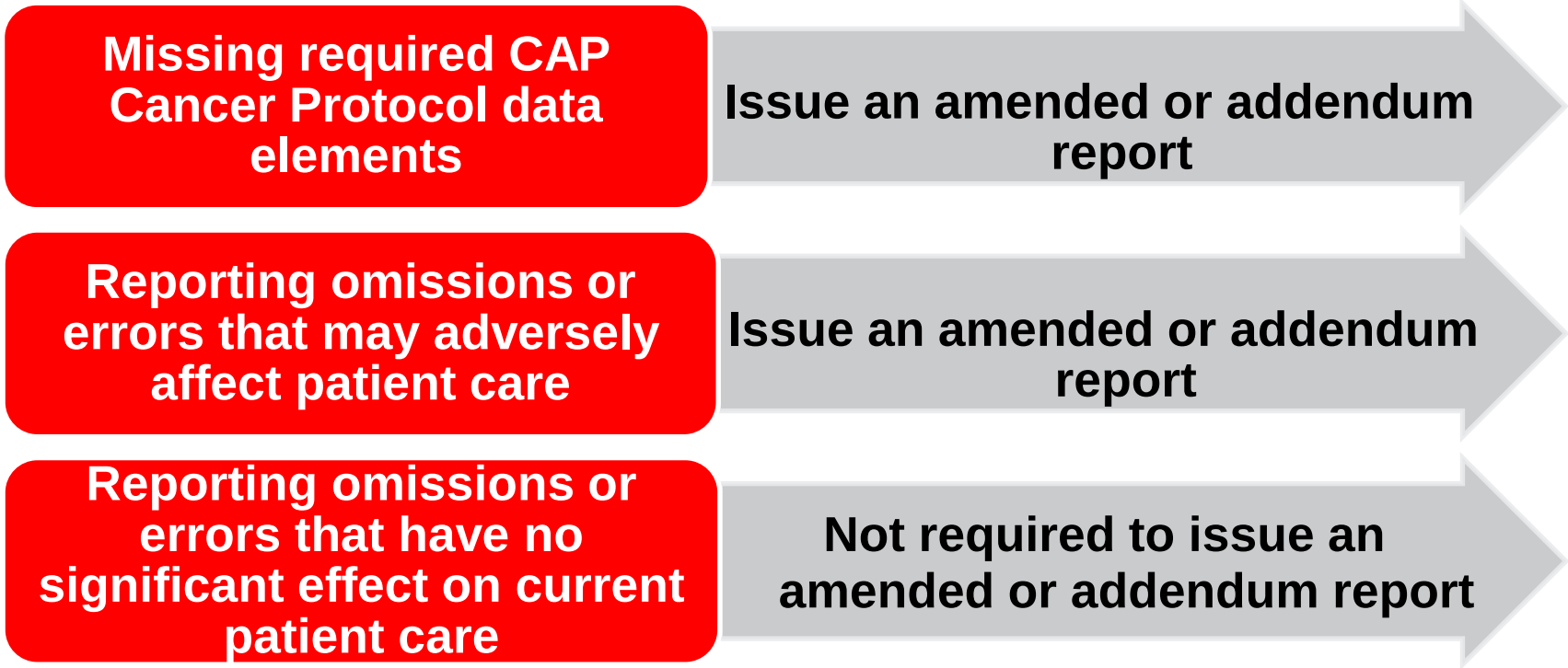
Frozen tissue submitted at time of initial diagnosis for specialized studies
Frozen tissue from lesions that have potential for additional studies using archived frozen tissue (eg, diffuse gliomas)
(NEW) Frozen sections where margins or lesions have been exhausted and no pertinent residual tissue remains
Mohs frozen sections

Exceptions are made at the discretion of the laboratory director, responsible pathologist, or Mohs surgeon.

Discipline-Specific Checklist Changes, cont'd

ANP.12350 Cancer Protocols

- Revised the **NOTE** to clarify steps to take when **reporting errors** are identified in the self-audit of surgical pathology reports.



Discipline-Specific Checklist Changes, cont'd

Transfusion Medicine

- **TRM.43605 Component Labeling-Final Inspection**
  - **NEW checklist item for component labeling requiring personnel to verify all information on the final label by either:**
    - **One trained member of the transfusion service using a validated system (eg, LIS) or**
    - **Two trained members of the transfusion service**
  - **Applies to all final labeling of blood and blood components (eg, five-day plasma)**

- **Hematopoietic Progenitor Cells Section**
  - **Requirements within section were renumbered and moved to follow Blood/Component Donor and Selection Collection section.**
  - **Added NEW requirements under the "Collection" subsection: TRM.48060, TRM.48070, and TRM.48090 and under the "Physical Facilities" section (TRM.60710).**

Discipline-Specific Checklist Changes, cont'd

Transfusion Medicine: Training and Competency

- **TRM.45254 Training and Competency for Donor Collection Personnel**
  - **Clarified that donor collection personnel must be trained and assessed for competency at least annually.**

- **TRM.50150 Training and Competency for Critical Tasks**
  - **NEW requirement added to focus on the training and competency for transfusion medicine personnel performing critical non-testing duties (eg, issuing blood components, modification of blood products).**
  - **Personnel must be assessed at least annually.**

- **Your laboratory director determines:**
  - **How competency is assessed**
  - **Qualifications of individual assessing competency**

What Does This Mean for My Laboratory?

- **Does competency assessment of donor collection personnel and personnel performing critical tasks need to include all six elements of competency as listed in GEN.55500?**

Using CAP Resources to Identify and Implement Changes

- **Checklist download on cap.org: e-LAB Solutions Suite (login required)**

Checklist Type
Master
Custom
Changes Only ✓

- **Focus on Compliance webinar series**
- **Fast Focus on Compliance: bite size learning**
- **CAP TODAY articles: view or subscribe on cap.org**
- **Checklist requirement Q&A (e-LAB Solutions Suite: Accreditation Resources)**
- **eAlerts posted on cap.org**
- **COVID-19 FAQs on cap.org**

Top 10 Deficiencies for 2019

CHECKLIST REQUIREMENT	CAP-WIDE*
COM.10000 Procedure Manual	1
GEN.55500 Competency Assessment -Nonwaived Testing	2
COM.01200 Activity Menu	3
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	4
COM.30600 Maintenance/Function Checks	5
COM.01700 PT and Alternative Performance Assessment Result Evaluation	6
COM.30300 Reagent Labeling	7
COM.04200 Instrument/Equipment Record Review	8
COM.01400 PT Attestation Statement	9
COM.30750 Temperature Checks	10

** Based on 2019 CAP inspection data*

Resources

- **Checklist interpretation questions?**
  - **Email: accred@cap.org**
  - **Phone: 800-323-4040, option 1**

Summary

- Summarized significant checklist changes.
- Provided a brief overview of changes to discipline-specific checklists.
- Provided a toolkit for you to review on your own.

Questions?